

Notice of Allowability

Application No.

10/616,477

Applicant(s)

ZELIGS, MICHAEL A.

Examiner

Nabila G. Ebrahim

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to RCE filed on 9/26/07.
2. ☒ The allowed claim(s) is/are 1-3, 5-7 and 15-24.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>9/26/07</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant representative, Mr. Thomas Friebe on 1/14/2008.

The application has been amended as follows:

Replace all previously amended claims with the following list of claims:

Listing of Claims:

1. (currently amended) A method of treating cervical dysplasia in a subject having cervical dysplasia comprising administering to the subject an amount of an indole selected from the group consisting of 3,3'-Diindolylmethane (DIM) and 2-(Indol-3-ylmethyl)- 3,3'-Diindolylmethane (LTr-1) effective to reduce one or more symptoms associated with cervical dysplasia, wherein the indole is formulated as a tablet, pill, capsule, suppository, cream, parenteral suspension or liposomal spray, or is suspended as microparticles in a starch carrier matrix.
2. (currently amended) The method of claim 1, wherein the indole is DIM.
3. (previously presented) The method of claim 2, wherein the DIM is suspended as microparticles in a starch carrier matrix.
4. (canceled)

5. (currently amended) The method of claim 20, 21 or 23, wherein the indole is administered by direct application to the vaginal or cervical mucosa of the subject.
6. (currently amended) The method of claim 20, 21 or 23, wherein the indole is administered transdermally.
7. (currently amended) The method of claim 17, 18 or 19, wherein the indole is administered orally.
- 8-14. (canceled)
15. (previously presented) The method of claim 1, wherein the subject is a human female.
16. (new) The method of claim 1, wherein the indole is LTr-1.
17. (new) The method of claim 1, wherein the indole is formulated as a tablet.
18. (new) The method of claim 1, wherein the indole is formulated as a pill.
19. (new) The method of claim 1, wherein the indole is formulated as a capsule.
20. (new) The method of claim 1, wherein the indole is formulated as a suppository.
21. (new) The method of claim 1, wherein the indole is formulated as a cream.
22. (new) The method of claim 1, wherein the indole is formulated as a parenteral suspension.
23. (new) The method of claim 1, wherein the indole is formulated as a liposomal spray.

24. (new) The method of claim 1, wherein the indole is suspended as microparticles in a starch carrier matrix.

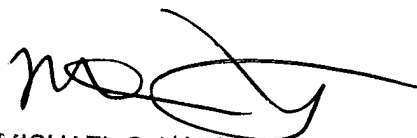
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
1/20/08


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER